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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|--------------------|
| 09/830,876 | 07/20/2001 | John Howard Skerritt | Q-64066 | 5306 |
| 7590 | 04/16/2004 | | EXAMINER | NGUYEN, BAO THUY L |
| Sghrue Mion Zinn Macpeak & Seas 2100 Pennsylvania Avenue NW Washington, DC 20037-3202 | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |
| DATE MAILED: 04/16/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/830,876 | SKERRITT, JOHN HOWARD |
| | Examiner | Art Unit |
| | Bao-Thuy L. Nguyen | 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 16-22 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper dated 9/15/2003.
2. Applicant's election with traverse of claims 1-15 in Paper dated 1/15/2004 is acknowledged. The traversal is on the ground(s) that the claims are joined by a special technical feature of an antibody that binds to an epitope of α -amylase comprising one or more of the amino acid sequences having SEQ ID NO. 1, 2 and 3. This is not found persuasive because the claims are not drawn to a single antibody that binds to an epitope of α -amylase comprising one or more of the amino acid sequences having SEQ ID NO. 1, 2 and 3; instead the claims are directed to polyclonal antibodies and fragments thereof, monoclonal antibodies and fragments thereof, recombinant antibody fragments or any other type of binding partners that can bind to SEQ ID Nos. 1-3. Even though the claims do recites that these various antibodies bind to an epitope of α -amylase comprising one or more of the amino acid sequences having SEQ ID NO. 1, 2 and 3, these antibodies are still different from one another because they have different physical, chemical and binding characteristics, therefore, they lack a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

3. This application contains claims drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-15, "An immunoassay" should be changed to -The immunoassay—for clarity.

Claim 1 is incomplete because it lacks a correlation step between the detected binding and the quality or quantity of alpha-amylase. The wherein clause of claim 1 is also confusing. It

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is recommended that this clause be amended as follows –wherein either of said first or second epitopes is an epitope comprising one or more [of the] amino acid sequences selected from the group consisting of SEQ ID 1, SEQ ID 2, SEQ ID 3 and immunogenic fragments that are ≥80% identical to SEQ ID Nos. 1-3. –

Claims 1 and 2 are vague and indefinite with respect to the recitation of variants showing certain sequence identity. First, it is unclear if the sequence identity is to the full length protein or if it refers to the sequences disclosed as SEQ ID 1, 2 and 3. Second, the term "variant" is unclear, it can encompass changes, substitutions, deletions and insertions; therefore, the metes and bounds of the claim cannot be understood. A single point mutation can abolish the entire function of the protein or changes of the conformation of the protein thus eliminate the ability of the antibody to recognize this altered epitope.

Claim 10 is vague and indefinite with respect to the recitation of "recombinant antibody fragments". The specification is silent on recombinant antibody or recombinant antibody fragments that can bind to SEQ ID Nos. 1-3.

Claim 14 is vague and indefinite because it is unclear how "suitable" is defined.

Claim 15 is confusing. It is unclear what is being claimed.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method to detect proteins comprising sequences with a given percent similarity to a protein. Selective point mutation to one key epitope residue could eliminate the ability of an antibody to recognize this altered epitope. If the range of

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decreased binding ability after single point mutation of a protein antigen varies, one could expect point mutations in the protein antigen to cause varying degrees of loss of detection, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of function. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool. Thus, proteins of different levels of homology may not be recognized by the antibody, and be ineffective in detecting said protein.

Therefore, the claimed subject matter has not been described in such a way as to convey to a skilled artisan that the inventor has possession of the claimed invention, mainly variants showing $\geq 80\%$ or $\geq 90\%$ sequence identity, either to SEQ ID Nos. 1-3 or to the full length protein.

Conclusion

7. No claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen
Primary Examiner
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